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In re

Patent Application of

Jeffrey John Kester, et. al.

Application No. 09/827,834

Confirmation No.: 6353

Filed: April 6, 2001

Examiner: Mojdeh Bahar

"COMPOSITIONS FOR REDUCING
HYPERCHOLESTEROLEMIA AND
CONTROLLING OF POSTPRANDIAL
BLOOD GLUCOSE AND INSULIN LEVELS"

I, Leslie Rector, hereby certify that this correspondence is being deposited with the US Postal Service as Express Mail, Label No. EV 086434488/US in an envelope addressed to Commissioner for Patents, Box RCE Washington, D.C. 20231, on the date of my signature.

Leslie Rector
Signature

February 27, 2003
Date of Signature

DECLARATION OF DR. JEFFREY J. KESTER UNDER 37 CFR 1.132

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

I, Jeffrey J. Kester, Ph.D., do hereby declare and state the following:

1. I am employed as a Research Fellow at Procter & Gamble, in the Snacks and Beverage Technology Division. I have been employed in this capacity for about 2 years, and have held prior research positions at Procter & Gamble since 1987. A copy of my Curriculum Vitae is attached as **Exhibit A**.

2. I am a co-inventor of the above-identified application.

3. It is my understanding that the claims of the above-identified application have been rejected by the Examiner under 35 U.S.C. § 103 over a combination of Jandaček (U.S. Patent No. 4,005,195), Akoh and an FDA announcement abstract.

4. As discussed in the specification of the present application, it was recognized in the art prior to the instant invention that the incorporation of beta-glucan soluble fiber in food compositions resulted in taste and process performance challenges. In particular, the incorporation of sufficient beta-glucan soluble fiber to meet Food & Drug Administration (FDA) requirements for heart health claims regarding food products was thought to be especially problematic for traditional snack foods. The reason for this is that while the required level of beta-glucan soluble fiber to meet the FDA requirement for a heart health claim is at least 0.75 gram per single serving (Code of Federal Regulations, Title 21, Part 101, Section 101.81), the typical and most economical whole-grain sources of this soluble fiber are not highly enriched in beta-glucan. For example, oat bran typically contains only about 5.5-7.5% beta-glucan and oat bran concentrate typically contains only about 11.5% beta-glucan (see product information sheets from The Quaker Oats Company, attached as Exhibit B). As a result, it requires relatively high levels of these whole-grain sources of beta-glucan in traditional snack food formulations in order to yield a finished product containing at least 0.75 gram beta-glucan per single serving.

5. To illustrate, a traditional snack food such as potato crisps with a single serving size of 30 grams requires that about 33% of the product (10 grams) consist of oat bran or 21.7% of the product (6.5 grams) consist of oat bran concentrate in order to meet the FDA requirements.

6. The difficulties in process and performance of these formulations are exacerbated even further when the traditional snack food contains a significant level of a non-digestible lipid, such as olestra. For example, a potato crisp that is fried in olestra may contain about 7.5 grams of olestra per 30 gram single serving (e.g., see Example 4 in the specification of the present application). Therefore, the whole-grain source of beta-glucan, such as oat bran or oat bran concentrate, must make up an even greater proportion of the non-lipid component of the traditional snack food, i.e., 10 grams out of 22.5 grams equaling about 44% for oat bran, or 6.5 grams out of 22.5 grams equaling about 29% for oat bran concentrate.

7. High levels of whole-grain ingredients in food products are known to contribute to processing and taste performance issues. For example, C.E. Stauffer, *Baking & Snack*, February 2000 issue, pg. 64-70, attached as **Exhibit C**, discusses how incorporation of whole grain sources of beta-glucan (such as oat bran) into baked goods may yield reduced volume and a denser texture. In addition, a recent article by J. Slavin and D. Kritchevsky, *Food Technology*, May 2002 issue, volume 56, page 216, attached as **Exhibit D**, promotes the incorporation of whole grains into food products, but states that "whole grains present multiple challenges for the food processor." This article further states that whole-grain ingredients constituting greater than 25% by weight of the flour creates processing problems. The article lists barriers described by consumers to the use of whole grains in foods, including "texture, dryness, and poor taste." Finally, the taste challenges associated with incorporating high levels of a viscous fiber, such as beta-glucan, into food products is highlighted in a chapter by D. Jenkins et al. (2001, in *Advanced Dietary Fiber Technology*, B.V. McCleary and L. Prosky, ed., pg. 162-167), attached as **Exhibit E**, which states that "the lack of readily available palatable formulations has made further work in this area difficult."

8. Notwithstanding the above-mentioned problems known to those skilled in the art, the selected traditional snack examples in the specification of the present application contain levels of whole-grain oat bran in excess of 30%. For example, the cracker formulation in Example 6 contains 38.5% oat bran concentrate by weight of the flour.

9. For the above reasons, it was surprising that my co-inventors and I were able to produce fabricated potato crisp dough and cracker dough comprising relatively high levels of beta-glucan containing whole-grain sources (oat bran), that were capable of being handled and sheeted during processing. Furthermore, it was assumed that the incorporation of both whole-grain sources of beta-glucan soluble fiber and non-digestible fats into traditional snacks would not result in palatable formulations that could make heart health claims under FDA guidelines.

10. It was also unexpected that finished traditional snack foods containing high levels of whole-grain sources of beta-glucan soluble fiber and non-digestible lipid, such as olestra, could be manufactured with taste properties essentially equivalent to their counterparts made

without beta-glucan soluble fiber and non-digestible lipid. Evidence of the good taste of potato crisps produced according the instant application is provided by the following sensory data, which compares crisps containing beta-glucan soluble fiber and olestra made according to Example 4 (Product B) to control crisps made without beta-glucan soluble fiber and olestra (Product A). The attribute ratings are the average scores from the sensory panelists on a 1-9 scale. Importantly, there is no significant difference ($p=0.05$) between the products in acceptability, thereby indicating that the overall quality of Product B containing beta-glucan soluble fiber and olestra is equivalent to the control Product A.

Sensory Test Results

Product A: Control potato crisp made without beta-glucan soluble fiber or non-digestible lipid

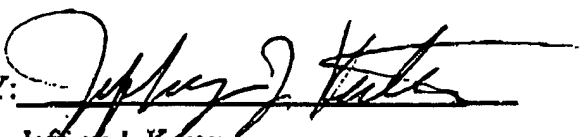
Product B: Potato crisp made with beta-glucan soluble fiber (0.8 g / 30 g potato crisps) and olestra (7.5 g / 30 g potato crisp)

	<u>Product A</u>	<u>Product B</u>
Base size	17	17
Overall flavor	4.8	4.7
Color	5.6	5.2
Crispy/Crunchy	7.0	5.4
Saltiness	3.8	4.1
Greasy mouth-coating	2.2	2.6
Uncharacteristic flavor	1.8	1.4
Acceptability	5.6	5.7

11. Thus, it was unexpected and contrary to prevailing assumptions that my co-inventors and I were able to develop formulations using both non-digestible fats and beta-glucan soluble fiber that were suitable for incorporation into a sheetable dough and that produced traditional snack foods that were surprisingly palatable.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements and the like so made are punishable by fine or imprisonment, or both, under Section 101 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

DATED: 2/26/2003

BY: 
Jeffrey J. Kester